Abstract 310

TITLE: Statistical Analysis of the CDC Model Performance Evaluation Program (MPEP) Human Immunodeficiency Virus (HIV) Rapid Test Laboratory Performance Data

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BACKGROUND: For more than a decade, rapid test (RT) methods have been developed that allow detection of human immunodeficiency virus (HIV) antibody (Ab) in about 15 minutes. For more than 7 years the MPEP has examined testing results for two FDA-approved rapid methods as well as many non-FDA-approved rapid methods. These data have been analyzed to (1) evaluate aggregate RT results, (2) determine demographic and testing characteristics of the laboratories performing RT methods, and (3) determine which characteristics may attribute to testing errors.
METHODS: The MPEP examined performance evaluation HIV-Ab RT results submitted by MPEP laboratories in 12 surveys from August 1992 through January 1998. Demographic and testing characteristics of laboratories using rapid methods were obtained from responses to survey questionnaires sent in August 1992, September 1995 and September 1997. Cross-correlational analyses were performed to determine if any specific laboratory demographics or testing characteristics were associated with HIV-Ab rapid method testing errors.
RESULTS: While the total number of laboratories (international and domestic) reporting RT results increased about 4-fold during the I2 survey period, the number of United States laboratories increased 10-fold during this period. Hospital laboratories have reported the greatest number of RT results, and diagnostic testing has been indicated as the most frequent purpose for using rapid methods. The average RT false-negative rate for all surveys was 8% (range 0.6%-23.4%) while the average false-positive rate was 2.7% (range 0.0%-9.2%). The highest percentage of error (range 2.7%-43.6%) was associated with false-negative test results being reported for weak positive HIV-Ab panel samples obtained from seroconverting donors. The aggregate false-negative error rate for weak positive HIV-Ab samples was more than 3 times greater than the aggregate enzyme immunoassay (EIA) error rate for the same samples.
CONCLUSIONS: There was no significant correlation between false-positive error rate or false-negative error rate for HIV-Ab strong positive samples and primary testing purpose. However, there was significant correlation ($p=0.006$) between false-negative error rate for HIV-Ab weak positive samples and primary testing purpose. There was significant correlation ($p=0.013$) between false-positive error rate and type of RT device and significant correlation between false-negative error rate and type of RT device for both HIV-Ab strong positive samples ($p=0.024$) and HIV-Ab weak positive samples $p=0.0001$). The aggregate rapid test false-negative error rate for weak positive HIV-Ab samples was significantly greater $p=0.009$) than the aggregate EIA false-negative error rate for the identical weak positive HIV-Ab samples tested by the same laboratory.

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